Senate Study Bill 3155 - Introduced

SENATE FILE _____
BY (PROPOSED COMMITTEE ON COMMERCE BILL BY CHAIRPERSON DAWSON)

A BILL FOR

An Act relating to pharmaceutical drug manufacturers and prescription drug prices, and including applicability provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. **510D.1 Definitions.**

As used in this chapter, unless the context otherwise requires:

1. *"Commissioner"* means the commissioner of insurance.

2. *"Dispenser"* means the same as defined in 21 U.S.C. §360eee(3).

3. *"Established name"* means the same as defined in 21 C.F.R. §299.4.

4. *"New prescription drug"* or *"new drug"* means a prescription drug approved by the United States food and drug administration for which a wholesale acquisition cost has not been previously established.

5. *"Newly acquired prescription drug"* or *"newly acquired drug"* means a prescription drug approved by the United States food and drug administration that has been researched and developed by an entity other than the pharmaceutical drug manufacturer that acquires the right to sell the prescription drug.

6. *"Patient assistance program"* means a program a pharmaceutical drug manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket cost for a prescriptions drug by using a coupon, discount card, pharmaceutical drug manufacturer debit card, or other means provided by the pharmaceutical drug manufacturer.

7. *"Pharmaceutical drug manufacturer"* or *"manufacturer"* means any person engaged in the business of producing, preparing, converting, processing, packaging, labeling, or distributing a prescription drug that is sold to any person in this state. *"Pharmaceutical drug manufacturer"* or *"manufacturer"* does not include a wholesaler distributor or a dispenser.

8. *"Prescription drug"* means the same as defined in 21 U.S.C. §360eee(12).

9. *"Price"* means the wholesale acquisition cost as defined in 42 U.S.C. §1395w-3a(c)(6)(B).

10. *"Wholesale acquisition cost"* means the same as defined

in 42 U.S.C. §1395w-3a(c)(6)(B).

11. *"Wholesale distributor"* means the same as defined in 21 U.S.C. §360eee(29).

Sec. 2. NEW SECTION. **510D.2 Pharmaceutical drug manufacturers — prescription drugs — reporting requirements.**

1. A pharmaceutical drug manufacturer shall submit the information pursuant to subsection 2 to the commissioner for each prescription drug manufactured by the manufacturer to which all of the following apply:

a. The price of the prescription drug is one hundred dollars or more for a thirty-day supply, or for a course of treatment lasting less than thirty days.

b. The price of the prescription drug increases an amount greater than the percentage increase in the most recent consumer price index published in the federal register by the United States department of labor, bureau of labor statistics.

2. Within sixty calendar days of the date of a price increase pursuant to subsection 1, paragraph *"b"*, the manufacturer shall submit, in the form and manner prescribed by the commissioner, all of the following information:

a. The established name and the brand name of the prescription drug, the current price of the prescription drug, and the net price increase of the prescription drug expressed as a percentage.

b. A statement detailing all factors that contributed to the price increase of the prescription drug and an explanation regarding the impact each factor had on the price increase.

c. The brand name of all generic versions of the prescription drug currently available on the consumer market.

d. The initial price of the prescription drug after it was approved by the United States food and drug administration.

e. If applicable, the annual net price increase, expressed as a percentage, of the prescription drug for each of the five immediately preceding calendar years.

f. For the immediately preceding twelve consecutive months,

the average price of the prescription drug in each of the ten countries outside of the United States with the highest sales of the prescription drug.

g. The aggregate direct and administrative costs incurred by the manufacturer related to any of the following:

(1) Manufacturing the prescription drug.

(2) Marketing and advertising the prescription drug.

(3) Researching and developing the prescription drug.

(4) Distributing the prescription drug.

h. The net revenue generated for the manufacturer attributable to the sale of the prescription drug during the immediately preceding twelve consecutive months.

i. The net profit generated for the manufacturer attributable to the prescription drug during the immediately preceding twelve consecutive months.

j. The aggregate cost to the manufacturer of any patient assistance programs associated with the prescription drug.

k. If applicable, the patent expiration date for the prescription drug.

l. If applicable, the exclusivity expiration date for the prescription drug.

m. Whether an agreement exists between the manufacturer and any another entity or entities requiring the other entity or entities to delay offering a generic version of the manufacturer's prescription drug on the open market.

Sec. 3. NEW SECTION. **510D.3 Pharmaceutical drug manufacturers —— new prescription drugs —— reporting requirements.**

1. A pharmaceutical drug manufacturer shall submit the information pursuant to subsection 2 to the commissioner for each prescription drug manufactured by the manufacturer to which any of the following apply:

a. The prescription drug is a new drug that has a price greater than five hundred dollars for a thirty-day supply.

b. The prescription drug is a generic new drug that has a

price greater than two hundred dollars for a thirty-day supply.

2. Within sixty calendar days of the first date the manufacturer offers the new drug in this state, the manufacturer shall submit, in the form and manner prescribed by the commissioner, all of the following information:

a. The price of the new drug.

b. The established name and the brand name of the new drug.

c. The brand name of the generic version, if applicable.

d. Whether the new drug received a breakthrough therapy designation from the United States food and drug administration.

e. Whether the new drug received a priority review designation from the United States food and drug administration.

f. The aggregate direct and administrative costs incurred by the manufacturer for all of the following:

(1) Manufacturing the new drug.

(2) Marketing and advertising the new drug.

(3) Researching and developing the new drug.

(4) Distributing the new drug.

g. If applicable, the patent expiration date for the new drug.

h. If applicable, the exclusivity expiration date for the new drug.

Sec. 4. NEW SECTION. **510D.4 Pharmaceutical drug manufacturers — newly acquired prescription drugs — reporting requirements.**

1. For each newly acquired prescription drug for which the net price increases by more than one hundred dollars on or after the date of a manufacturer's acquisition of the new drug, the acquiring manufacturer shall submit to the commissioner, within sixty calendar days of the date the acquiring manufacturer offers the newly acquired drug in this state, all of the following information:

a. The date on which the newly acquired drug was acquired.

b. The price of the newly acquired drug on the date of acquisition.

c. If applicable, the average price of the newly acquired drug during each of the twelve consecutive months immediately preceding the date of acquisition.

d. If applicable, the average net price of the newly acquired drug during each of the five consecutive calendar years immediately preceding the date of acquisition.

e. The identity of the entity from which the acquiring manufacturer acquired the newly acquired drug.

f. The date that the newly acquired drug was originally offered on the consumer market and the price of the newly acquired drug on that date.

g. Whether an agreement exists between the manufacturer and any another entity or entities requiring the other entity or entities to delay offering a generic version of the manufacturer's newly acquired drug on the consumer market.

h. If applicable, the new drug's patent expiration date.

i. If applicable, the new drug's exclusivity expiration date.

Sec. 5. NEW SECTION. **510D.5 Prescription drug pricing — public availability.**

1. Information provided by a pharmaceutical drug manufacturer to the commissioner pursuant to sections 510D.2, 510D.3, and 510D.4 that may reveal any of the following as related to a specific prescription drug or class of prescription drugs shall be considered a confidential record, and be recognized and protected as a trade secret pursuant to section 22.7, subsection 3:

a. The amount the manufacturer charges a specific health carrier, specific pharmacy benefit manager, or a specific dispenser.

b. The dollar value of the rebates the manufacturer provides a specific health carrier, specific pharmacy benefit manager, or a specific dispenser.

c. The identity of a specific health carrier, specific pharmacy benefit manager, or a specific dispenser.

2. Within sixty calendar days of receipt, the commissioner shall publish the nonconfidential information provided pursuant to sections 510D.2, 510D.3, and 510D.4 on a publicly accessible internet site.

Sec. 6. NEW SECTION. **510D.6 Rules.**

The commissioner may adopt rules pursuant to chapter 17A as necessary to administer this chapter.

Sec. 7. NEW SECTION. **510D.7 Enforcement.**

The commissioner may take any action within the commissioner's authority to enforce compliance with this chapter.

Sec. 8. APPLICABILITY.

1. The section of this Act requiring a manufacturer to submit a report regarding existing prescription drugs to the commissioner applies to a manufacturer that sells a prescription drug to any person in this state on or after July 1, 2020.

2. The section of this Act requiring a manufacturer to submit a report regarding new prescription drugs to the commissioner applies to a manufacturer that sells a new prescription drug to any person in this state on or after March 15, 2021.

3. The section of this Act requiring a manufacturer to submit a report regarding newly acquired prescription drugs to the commissioner applies to a manufacturer that sells a newly acquired prescription drug to any person in this state on or after July 1, 2021.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to pharmaceutical drug manufacturers and prescription drug prices.

If the price of a prescription drug is $100 or more for a

30-day supply or for a course of treatment lasting less than 30 days; or the price of a prescription drug increases by an amount greater than the percentage increase of the most recent consumer price index published by the United States department of labor, bureau of labor statistics, the bill requires a pharmaceutical drug manufacturer (manufacturer) to submit a report to the commissioner of insurance (commissioner) that includes information as outlined in the bill. The report must be submitted within 60 calendar days of the date of the applicable price increase. "Price" is defined in the bill as the wholesale acquisition cost of the drug. "Wholesale acquisition cost" is the manufacturer's list price for a drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data. "Pharmaceutical drug manufacturer" or "manufacturer" is defined in the bill as any person engaged in the business of producing, preparing, converting, processing, packaging, labeling, or distributing a prescription drug that is sold to any person in this state. The definition does not include a wholesale distributor or a dispenser, both of which are also defined in the bill.

If a manufacturer's new drug has a price greater than $500 for a 30-day supply, or a generic new drug that has a price greater than $200 for a 30-day supply, within 60 calendar days of the first date the manufacturer makes the new drug available in this state, the manufacturer must submit a report to the commissioner that contains the information outlined in the bill. The bill defines "new prescription drug" or "new drug" as a prescription drug approved by the United States food and drug administration for which a wholesale acquisition cost has not been previously established.

For each newly acquired prescription drug for which the net price increases by more than $100 on or after the date of

a manufacturer's acquisition of the new drug, the acquiring manufacturer must submit a report to the commissioner, within 60 calendar days of the date the acquiring manufacturer offers the newly acquired drug in this state, that contains information as detailed in the bill. "Newly acquired prescription drug" or "newly acquired drug" is defined in the bill as a prescription drug approved by the United States food and drug administration that has been researched and developed by an entity other than the pharmaceutical drug manufacturer that acquires the right to sell the prescription drug.

Within 60 calendar days of receipt, the bill requires the commissioner to publish the nonconfidential information, as described in the bill, from the required reports filed by manufacturers on a publicly accessible internet site.

The commissioner may adopt rules as necessary to administer the provisions contained in the bill. The commissioner may also take any action within the commissioner's authority to enforce compliance with the provisions contained in the bill.

The section of the bill requiring a manufacturer to submit a report regarding existing prescription drugs to the commissioner applies to a manufacturer that sells a prescription drug to any person in this state on or after July 1, 2020. The section of the bill requiring a manufacturer to submit a report regarding new prescription drugs to the commissioner applies to a manufacturer that sells a new prescription drug to any person in this state on or after March 15, 2021. The section of the bill requiring a manufacturer to submit a report regarding newly acquired prescription drugs to the commissioner applies to a manufacturer that sells a newly acquired prescription drug to any person in this state on or after July 1, 2021.